MR. CHAIRMAN; Question, No. 182.

*182. *The questioner (Shri Virendra Verma) was absent. For answer* vide col. 36-37 infra]

Commtttee to Consider the price control on Drugs.

* 183. SHRI MOHD. KHALEELUR RAHMAN:
CHOWDHARY RAM SEWAK: t

Will the Minister of INDUSTRY be pleased to state;

(a) whether it is - a fact that, to reconsider future decontrol on ground of Research and Development the Kelkar Committee suggested appointment of a permanent committee;

(b) if so, whether his Ministry has constituted such a committee;

(c) if so, what are its terms of reference;

(d) whether it is also a fact that drugs recommended for price decontrol by the Kelkar Committee have been referred to the said committee; and

(e) if so, what are the details thereof?

THE MINISTER OF INDUSTRY (SHRI J. VENGAL RAO): -fa) to- (e) A Statement is laid on the Table of Rajya Sabha.

Statement

in pursuance of the recommendations contained in the Supplementary Report of the Kelkar Committe (Copies of which are available in the Parliament Library), an inter-ministerial Expert Committee has already been constituted to assess the claims of manufacturers for exempting, from Price Control under DPCO, 1987, the drug(s) as is/are produced by that manufacturing unit from the basic stage by a process of manufacture developed through its own Research & Development effort for a specified period of not exceeding 5 Years, reckoned from the date of commencement of commercial production of such bulk *drug (s)* subject to certain conditions Specific guidelines in this regard have also- been issued. Copies of the relevant Orders/Guidelines are enclosed at Annexure I and II.

(d) and (e) All manufacturers (including those whose cases were already cansidered' by the Kelkar Committee) claiming exemption On the above ground are required to apply to the said Expert Committee, in accordance with the provisions of the Guidelines, in order to ensure uniformity of approach.

Annexure-I

F.No;. 4(8)/87—PI(if) Part
GOVERNMENT OF INDIA
MINISTRY OF INDUSTRY
DEPARTMENT OP CHEMICALS & PETROCHEMICALS
OFFICE OF THE DEVELOPMENT COMMISSIONER(PI)
NEW DELHI, the 14th February, 1989
GUIDELINES NO. 1/1989

In excercise of the powers conferred by Paragraph 25 of the Drugs (Prices Control) Order, 1987, (hereinafter called the "Said Order"), the Central Government hereby issue Guidelines for the purpose of grant of exemption under Para 28 of the said order to such bulk drug manufacturing unit from the provisions of Para 3 of the said Order in respect of such bulk durgs) as is/are produced by that unit from the basic stage by a process of manufacture developed though its own Research and Develppment effort, for a specified, period not exceeding five years reckoned from the date of commencement of commercial production of such, bulk drug(s) subject *to* the following, namely :-------

(i) The process development activities are registered with the Department of Scientific and Industrial Research (herein after referred to. as DSIR) and a Certificte is

t The question was actually asked on the floor of the House by Chowdhary Ram Sewak.

issued by DSIR to the effect that the manufacturer has developed the process of manufacture through its own R&D efforts.

(ii) The process so developed is significantly different from the known/available technology in the country leading to import substitutions/cost reduction etc.

(iii) The manufacturer shall make an application to the Government within 30 days of commencement of commercial production of such bulk drug or within 30 days of the date of issue of these guidelines in the case of bulk drugs already under production, as the case may be, alongwith the information as per the Annexure, and such other information as may be required by the Government and/or such additional information as the company may voluntarily furnish.

(iv) The Government if satisfied with the application mentioned above, may be a Notification in the Official Gazette, exempt a manufacturer from fixation of price or compliance with the price already fixed if any for such a bulk drug under the provisions of the said Order.

(v) In case of bulk drugs which are already being produced from the basic stage by a process of manufacture developed through indigenous Research and Development, the period which has already elapsed since it came into commercial production by this process shall count towards determining the said limit of five years prescribed under this Order.

(vi) In case of processes developed by National Laboratories and purchased and actually made use of by a manufacturer such activity shall also betaken into consideration for the purpose of granting exemption.

(vii) The Government shall have the liberty to withdraw the exemption so granted at any time.

(viii) After expiry of the period of exemption, the manufacturer shall submit application(s) in Form-I of the Drugs (Prices Control) Order, 1987 for fixation of price of such a bulk durg(s) under the provision of the said Order.

Sd/-

(R.S. MATHUR)
Joint Secretary to the Govt, of India.

To

1. All Pharmacetical Industry Associations.
2. B.I.C.P.

CIRCULATED

Sd/-

(L.K. MALHOTRA)
Director(PI)
14-2-1989

No. F. 4/8/87-PI(II)-Part

GOVERNMENT OF INDIA

MINISTRY OP INDUSTRY

DEPATMENT OF CHEMICALS AND PETROCHEMICALS

OFFICE OP THE DEVELOPMENT COMMISSIONER (PI)

NEW DELHI, the 14th February, 1989.

MEMORANDUM

It has been decided to constitute the following Expert Committee to examine the applications received *from* various manufacturers for exemption of balk drug(s) from Price Control as provided under paragraph 28(2) (e) of Drugs (Prices Control) Order, 1987.

1. Shri K.M. Kaul, Project Officer (PI), Department of Chemicals & Petrochemicals, Sastri Bhavan, New Delhi .....Chairman
2. Dr. Rajendra Prasad, Principal Scientific Officer,' Department of Science Industrial Research, Technology Bhawan, New Mehrauli Road, New Delhi .....Member
3. Shri Y.B. Tel-ang Deputy Director, Bureau of Industrial Costs & Prices Lok Nayak Bhawan (7th floor) New Delhi.....Member
4. Shri J.M. Garg Development Officer (Chem.) D.G.T.D., Udyog Bhawan, New Delhi .....Member

2. The Committee will examine the various applications received from time to time and make necessary recommendations..

Sd/-

(R.S. MATHUR)

Joint Secretary to the Govt, of India.

CIRCULATED

Sd/-

(L.K. MALHOTRA

DIRECTOR (pI)

To

1. The Members of the Expert Committee
2. The concerned Head of the Departments.

Annexure

(Information to be furnished (in five copies) for exemption of bulk durg from price control under Para 28 of DPCO, 1987)

1. Name and address of the applicant;
2. Status and activities.
3. Details of recognition granted by DSIR :
   (i) Date of recognition and validity period,
   (ii) Research and Development Programmes proposed in the application for recognition with DSIR;
   (iii) Date of issue of certificate by DSIR regarding development of processes for the manufacture of bulk drug (copy to be enclosed);
4. Name of the bulk drug for which exemption is claimed and details of industrial approval held;
5. Dates of commencement and completion of R&D.
   (i) Laboratory scale.
   (ii) Pilot scale.
   (iii) Commercial trials.
6. Date of commencement of commercial production and quantity produced year-wise'.
7. Brief details of the process developed;
8. Details of significant improvements over the processes already available, if any, in the country.

9. Quantity benefits in terms of

(i) Import substitutions ;

(ii) Cost reduction ;

(iii) Any other .

10. Details of cost data and the proposed price as per Form I A of DPCO, 1937 .

11. Any other details in support of the claim for exemption:

(The information furnished in this form is to be certified by the authorised signature of the company).

Sd/-

(R.S. MATHUR)

Joint Secretary to the Govt, of India.

CHOWDHARY RAM SEWAK: Sir, Kelkar Committee adopted one of the exclusion criteria based on the development of indigenous technology and commencement of commercial production of bulk drug from basic stage. This principle was adopted to encourage development of indigenous " technologies, production from basic stages to make the industry strong, to attain the objective of self sufficiency in drug industry. In the supplementary report submitted to the government in the month of October, 1988, Kelkar Committee recommended price decontrol of seven bulk drugs based on this exclusion principle after verifying documentary evidences in support of each of seven bulk drugs in respect of development of indigenous technology and commencement of commercial production from basic stage. Kelkar Committee has stated in the supplementary report that the recommendation for exclusion of drugs is being made after the committee is fully satisfied. I would like to know from the hon. Minister why these drugs have not been price decontrolled so far and what are the reasons for delay when his Ministry has deleted fourteen drugs from price control on 18th January. 1989 based on the recommendation of Kelkar Committee in the supplementary report. What are the reasons for adopting a policy of pick and choose which leads to corruption?

SHRI J. VENGAL RAO. Sir, the question required information about the Government orders and it is completely and on the Table of the House. The h°n. Member mentioned about the exemption of 14 bulk drugs. These bulk drugs belong to the category of exempted drugs. Four durgs were transferred from the 1st Schedule to the IInd Schedule. The remaining recommendations are under the consideration of the Government and a decision will be taken soon.

CHOWDHARY RAM SEWAK: I would like to know from the hon. Minister the reasons for asking the producers of drugs to apply whose cases were already recommended for price decontrol based on the exclusion criteria of development of technology after verification and satisfaction of the members of Kelkar Committee for reference to a committee for review and examination by a committee which has been suggested by Kelkar Committee for assessment of future claims or claims where committee was either not satisfied or the drug producers could not submit documentary evidence as required and which is composed of much Junior Officer? in comparison to members of Kelkar Committee which consists of high officials and well-known experts. How are the findings of the high-level Committee are being put for review and examination to a Committee consisting of junior offi-

cers which took such a decision and why has a separate procedure has been adopt, ed for recommendations based on indigenous technology development when none of the other recommendations of the Kelkar Committee has been referred to any such committee?

SHRI J. VENGAL RAO: Sir, the Kelkar Committee's recommendations are not mandatory on the Government and the Government has got the power to appoint another commitee to verify whether these are manufactured with the indigenous R & D and they are verifying it. If it is correct, we will certainly give exemption.

MR. CHAIRMAN: Yes, Dr. Mahishi.

DR. (SHRIMATI) SAROJINI MAHISHI: Sir, the Minister's answer is not at all satisfactory. When you appoint a high-level Committee, naturally, the recommendations of that Committee have to be considered. To find out a new technology for a new drug requires an investment of about Rs. 100 crores and in the foreign countries it is a continuous process and it is going on. In our country, it is very rarely that the private companies or the other people are able to invest this much. But when we are investing something and the technology is also being found out and the Kelkar Cornmittee also has re. commended seven drugs, what is the point in not putting them out of the control list also and giving them exemption? These incentives have' got to be given for R&D in our country so that new technology can, be developed in our country. Therefore, the Ministry has to adopt a continuous and consistent policy, whether it is the Price Control Order of 1979 or the price Control Order of 1989, and what is being done in a period of ten years exactly to find out indigenous technology, the Ministry must be able to tell us.

SHRT T. VENGAL RAO: Sir. I entirely agree with the honourable Member. If they produce drug., with indigRenous R& D. certainly they will set exemption for five years and after five years only we will control the price. I have placed the orders on the Tabic of the House and we are taking a decision as early as possible on the basis of these facts.

MR. CHAIRMAN; Next Question. Question No. 184.

Wireless j Radio Telephone System in remote villages

*184. DR. YELAMANCHILI SIVAJI: Will the Minister of COMMUNICATIONS be pleased to state;

(a) whether there is any proposal to connect the remote villages by wirelessl radio telephone system;

(b) if so, what are the details thereof and

(c) by when the same will be implemented?

THE MINISTER OF STATE IN THE MINISTRY OF COMMUNICATIONS (SHR GIRIDHAR GOMANGO): (a) to *(c)* A Statement is laid on the Table of the House.

Statement

(a,) and (b) In 1982-8.3 under a Pilot Project, some Multi Access Radio Systems were importer for field trial in the country. Now ITI and GCEL are producing these systems after technology transfer and the supply has commenced from 1988-89. The number of Long Distance Public Telephones under MARR opened as on 31.3.19.89 are 424. Recently, TRC has developed a low capacity system 2[15 which is under field trial.

(c) It is proposed to connect remote villages by 2000AD subject to availability of equipment and resources.

DR. YELAMANCHILI SIVAJI Sir, it is mentioned in the statement that under a Pilot Project, some Multi Access Radio Systems were imported for field trials In the country I would like to know from' the thonoumbte Member from which country these were imported, how many numbers hare been imported, how much